IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff and Counter-Defendant, v. LUPIN LTD., LUPIN PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC. Defendants and Counter-Plaintiffs.	C.A. No. 2:10-cv-00080-FSH-PS C.A. No. 2:10-cv-01234-FSH-PS
TEVA WOMEN'S HEALTH, INC., Plaintiff and Counter-Defendant, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., and FAMY CARE LTD. Defendants and Counter-Plaintiffs.	**DOCUMENT FILED ELECTRONICALLY**

REPLY MEMORANDUM IN SUPPORT OF APPEAL FROM THE MAGISTRATE JUDGE'S ORDER DENYING LUPIN'S MOTION FOR LEAVE TO AMEND PATENT INVALIDITY CONTENTIONS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

Other Authorities

INTRODUCTION

Pursuant to Local Civil Rule 72.1, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") submit this reply memorandum in support of Lupin's appeal of the Honorable Patty Shwartz's order denying Lupin leave to amend its patent invalidity contentions. (*See* D.I. 136.)

ARGUMENT

I. Because Judge Shwartz's Dismissal of Lupin's Motion Is Dispositive, The Dismissal Must Be Reviewed *De Novo*.

Plaintiff Teva Women's Health's ("Teva's") opposition brief attempts to shoehorn the present facts into a scenario that justifies a deferential standard of review. Teva suggests that Lupin's invalidity contentions are merely "a mechanism for shaping the conduct of discovery," and that Judge Shwartz's order "did not effectively dismiss Lupin's anticipation claim and defense." (*See* D.I. 150, Teva's Op. Br. at 3–4.) In order to make this argument, Teva conjures a hypothetical situation in which Lupin later discovers "truly new" prior art that anticipates the patent claims, and thus is able to move (again) to amend its contentions and present an anticipation defense on the merits. (*See* Teva's Op. Br. at 3–4.) Under the actual and undisputed facts of the case, however, Lupin *has* discovered new prior art and finds itself with a statutory defense that it properly incorporated into the litigation under Rule 15 of the Federal Rules of Civil Procedure, but which it cannot litigate on the merits due to the Magistrate Judge's order. Such is the very definition of "dispositive." *See* Black's Law Dictionary 540 (9th ed. 2009) (defining "dispositive" as "being a deciding factor").

Teva overreaches when it argues that "Lupin itself has treated its motion to amend . . . as a non-dispositive discovery motion," noting that Lupin filed a joint letter rather than a formal motion. (*See* Teva's Op. Br. at 4.) As Teva knows, Magistrate Judge Shwartz explicitly directed

the parties to file a joint letter regarding leave to amend contentions, rather than a formal motion or a submission with other miscellaneous discovery disputes. (*See* D.I. 103, Status Hr'g Tr. 66–67, Oct. 28, 2010.) Lupin's compliance with Judge Shwartz's preferred procedure is simply not probative of whether Judge Shwartz's order is dispositive.

In short, Judge Shwartz' denial of Lupin's motion to amend its contentions should be reviewed without deference. That denial is dispositive of a defense, and Lupin's actions in connection with the motion are entirely consistent with that conclusion. Moreover, an error of law underlies the denial of Lupin's motion. Even under the "clearly erroneous or contrary to law" standard that Teva champions, *all* legal conclusions are reviewed *de novo*. *Doe v. Hartford Life & Ace. Ins. Co.*, 237 F.R.D. 545, 547–48 (D.N.J. 2006). As Lupin established in its earlier memorandum—a conclusion Teva that did not address in its opposition—the *only* factual finding at issue here is the Magistrate Judge's determination as to whether Lupin exercised diligence in seeking to amend; the remaining issues are subject to *de novo* review regardless of which standard this Court applies.

II. The Magistrate Judge's Conclusion Of A Lack of Diligence Is Contrary To Law, And Is Clearly Erroneous.

Teva argues that the Court should analyze diligence by focusing on when Lupin *should* have recognized the existence of an anticipation defense based on the German counterpart of the '749 patent. Although there is language in O_2 *Micro* that arguably suggests a should-have-known inquiry, in fact the O_2 *Micro* court addressed diligence measured from the point of *actual* discovery. *See* O_2 *Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1367–68 (Fed. Cir. 2006). Under that proper measure, Lupin acted diligently.

Lupin discovered and first appreciated the significance of the claims of the German application in late August 2010, when Lupin independently obtained an English translation of the

claims.[1] (*See* D.I. 125, Declaration of Sailesh K. Patel in Support of Lupin's Motion to Amend its Invalidity Contentions.) Lupin's discovery was made in the midst of efforts to investigate and understand the '749 patent's disclosure of both a "maximum of 77 days" and a "maximum of 84 days" of hormone administration, including a review of over twenty foreign counterparts of the '749 patent. (*See* Ex. LUP-3, Delphion Report for the '749 Patent, which shows foreign counterparts in AT (Austria), BR (Brazil), CN (China), CZ (Czech Republic), and through the alphabet to ZA (South Africa).)

Lupin then moved to amend its Answer on October 8, 2010 to add the anticipation defense based on the German counterpart, only a bit more than a month after the discovery. Lupin's next steps depended on Magistrate Judge Shwartz's preferred procedure for amendment of contentions, which was discussed at the October 28, 2010 status hearing.[2] As noted above, the Magistrate Judge directed the parties to submit any request to amend contentions by joint letter by November 29, 2010 (rather than by formal motion or as a discovery dispute). Lupin, Watson, Mylan and Teva then coordinated efforts to prepare initial positions, responses, and replies for the ultimate joint letter totaling forty-five pages and submitted on November 29. (*See* D.I. 112.)

[1] Teva suggests that Lupin should have moved to amend its contentions back in November 2009, when Lupin independently obtained a copy of the German Application *in German* and received an informal translation of limited portions of the specification from an in-house translator. Teva glosses over the key fact: Lupin's motion to amend is based solely on the *claims* of the German Application, which Lupin did not have in English until a translation was produced on June 30, 2010 (along with 45,000 other documents—not pages, documents).

[2] In particular, Lupin needed guidance as to whether it should address the amendment in the joint letter regarding discovery disputes, as a formal motion, or as a separate informal application by joint letter. (*See* D.I. 40 at 3; D.I. 103.)

Under the correct legal standard, this timeline of activities—all of which occurred in the midst of document discovery and before a single deposition was taken—establishes Lupin's diligence. While Teva characterizes the interval as five months from production of the complete translation of the German counterpart (*see* Teva's Op. Br. at 10), the relevant interval for evaluating diligence—between discovery of the evidence and amendment of the Answer to incorporate that evidence—is (as described above) a little over a month.

Moreover, the diligence inquiry cannot be performed in a vacuum, but must be context-dependent. The Local Patent Rules do not define a particular time period that constitutes diligence—i.e., one month is diligent and two months is not—precisely because a party's diligence depends upon a variety of factors, including the procedural stage of the litigation. Common sense dictates that diligence in the midst of the discovery period will generally require something different from diligence on the eve of trial. Given that the Local Patent Rules do not provide a strict time cut-off, the basic tenets of commonsense and fair play necessarily fill in the contours of the Rules. Here, Lupin has proceeded logically, fairly, and without undue delay, well before the close of fact discovery, to address an important new prior art reference; thus, Lupin has acted diligently.

Even under Teva's legally erroneous "should have known" standard, Lupin should prevail. Teva basically contends that Lupin should have recognized earlier what no other defendant understood—namely, that the claims of the German counterpart differed materially from those of the '749 patent. (*See* Teva Op. Br. at 8 n.2.) While Teva points to the file history of the '749 patent as evidence that should have put Lupin on notice about the content of the German counterpart of the '749 patent, (Teva Op. Br. at 9), Teva admits that the file history of

the '749 patent would lead a reasonable party away from the conclusion that the German counterpart was materially different from the U.S. version:

> Further, Lupin incorrectly asserts that the German Application discloses administering 84 daily doses of combination pills. Rather, the file history of the related '749 patent establishes the exact *opposite* fact—the '749 patent (and by extension its counterpart German application) should be understood as *not* disclosing a maximum of 84 daily doses of combination pills, but instead disclosing a maximum of 77 daily doses.

(Teva Opp. Br. at 9–10.) Teva frames the "good cause" inquiry so as to impose an impossible diligence burden on Lupin. For example, Teva emphasizes that "Lupin first received the German Application as well as translations of portions thereof in November 2009," and that "Lupin's request to amend its Contentions was not submitted until November 2010, a year after it first received the German Application . . . ." (Teva Opp. Br. at 9.) But without an English translation of the *claims* of the German Application, Lupin had no way to appreciate the important difference between the '749 patent and the German Application—namely, the *claiming* of 84 days of hormone administration, just as in the claims of the patent-in-suit.

In sum, the Magistrate Judge's finding of a lack of diligence is both contrary to law and clearly erroneous. Lupin acted quickly upon discovery of the evidence, and a reasonable party in Lupin's position—by Teva's own argument—would have been led away from that discovery by the available information.

III. Lupin's Showing Of Diligence Is More Than Sufficient In Light Of The Lack Of Prejudice To Teva And The Purpose Of The Local And Federal Rules.

Given Lupin's showing of diligence, the denial of Lupin's motion is particularly troubling in light of the purpose of the Local Patent Rules and the lack of prejudice resulting from the proposed amendment. Teva's own inconsistent position underscores this tension. On the one hand, Teva recognizes that the German Application is "nearly identical" to the '749 patent already at issue in the litigation; on the other hand, Teva claims that permitting Lupin to

amend to assert this "nearly identical" application would somehow prejudice Teva.[3] (*See* Teva Op. Br. at 9, 11 & n.3.) But Teva does not, and cannot, provide a single concrete example of any actual prejudice that would result; instead, it provides only a vague and conclusory statement that Teva will be "forced to expend significant resources revising its positions and litigation strategy." (Teva Op. Br. at 11.)

Just how Teva would be forced to expend significant resources to defend against a reference that Teva believes is "nearly identical" to a reference already being asserted is unclear. Indeed, the German Application streamlines the litigation and resolves a dispute about the disclosures of the prior art. And as courts have recognized, prejudice "does not mean inconvenience to a party" or simply any development that harms a party's case. *See LePage's Inc. v. 3M*, No. Civ. A. 97-3983, 1998 WL 631960, at *3 (E.D. Pa. Sept. 2, 1998) (discussing prejudice in the context of Rule 15, and noting that "a mere claim of prejudice is not sufficient" and that "it is obvious that an amendment designed to strengthen the movant's legal position, will in some way harm the opponent") (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 488 (3d Cir. 1990)). Rather, prejudice requires "some showing that [the opposing party] was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the . . . amendments been timely." *Id.* Teva has not, and cannot, make that showing here.

In fact, the "sort of prejudice" the Local Patent Rules were designed to avoid is not at issue in this case. Lupin's amendment cannot be characterized as "the vexatious shuffling of

[3] While Teva recognizes that Watson is already asserting an anticipation defense based on the '749 patent, and while Teva recognizes that the '749 patent and the German Application are "nearly identical," Teva nonetheless concludes that because "Watson's anticipation defense is based on the '749 patent, not the German Application," Teva would suffer prejudice if Lupin were granted leave to amend. (Teva Op. Br. at 11 n.3.)

positions," and given that fact discovery remains open (indeed, depositions have not even been scheduled), it is clear that Lupin is not attempting to "shift[] . . . theories in reaction to adverse substantive rulings, . . . or late in discovery, leaving the opposing party with little time to conduct discovery on a new theory." *See O2 Micro*, 467 F.3d at 1365–66 (Fed. Cir. 2006); *Yodlee, Inc. v. CashEdge, Inc.*, No. 05-01550, 2007 WL 1454259, at *2–*3 (N.D. Cal. May 17, 2007).

Given this lack of prejudice and the admitted fact that granting Lupin's motion to amend its contentions would result in no new discovery and no delay in the litigation, a denial of Lupin's amendment would turn the Local Patent Rules from a case management tool into a punitive trap that the liberal pleading rules of the Federal Rules of Civil Procedure were meant to avoid. Indeed, because Lupin's motion to amend its Answer to assert an anticipation defense based on the German counterpart has already been granted, to deny Lupin's appeal is to effectively conclude that the Local Rule trumps the Federal Rule, even when one of the objectives of the Federal Rules—"to secure the *just*, speedy and inexpensive determination of every action"—would be frustrated by denial of the motion to amend. *See* Fed. R. Civ. P. 1 (emphasis added).

CONCLUSION

As set forth above and in Lupin's earlier memorandum of law, Lupin has established both that it acted diligently in seeking leave to amend its contentions, and that this amendment would not prejudice Teva in any meaningful way. Thus, regardless of the standard of review, Lupin has established both "good cause" and a "timely application" under Local Patent Rule 3.7. Lupin therefore respectfully requests that this Court reverse the Magistrate Judge's order and permit Lupin leave to amend its contentions.

Respectfully submitted,

Dated: February 14, 2011

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing Reply Memorandum In Support of Lupin's Appeal from the Denial of Lupin's Motion to Amend Patent Invalidity Contentions was served to the following persons by email on February 14, 2011:

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